ROZUCOR B

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ROZUCOR B [Bempedoic Acid and Rosuvastatin Tablets (180 mg+10 mg) (180 mg +20 mg)]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:
MECHANISM OF ACTION: *Bempedoic acid*: is an adenosine triphosphate-citrate lyase (ACL) inhibitor that lowers low-density lipoprotein cholesterol (LDL-C) by inhibition of cholesterol synthesis in the liver. *Rosuvastatin*: Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol.

INDICATIONS: ROZUCOR B 10/ ROZUCOR B 20 is indicated for the treatment of hypercholesterolemia.

DOSAGE AND ADMINISTRATION: *Dosage*: The recommended dose is one tablet daily. Each film-coated tablet contains a fixed dose of Bempedoic Acid and Rosuvastatin. *Method of administration*: Bempedoic Acid and Rosuvastatin Tablets should be given orally once daily with or without food

CONTRAINDICATION: In patients with hypersensitivity to Bempedoic acid or Rosuvastatin or to any of the excipients: - in patients with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 times the upper limit of normal (ULN). - In patients with severe renal impairment (creatinine clearance <30 ml/min). - In patients with myopathy. - In patients receiving concomitant combination of sofosbuvir/velpatasvir/voxilaprevir - In patients receiving concomitant ciclosporin. - During pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures. - Moderate renal impairment (creatinine clearance < 60 ml/min) – Hypothyroidism - Personal or family history of hereditary muscular disorders - Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate - Alcohol abuse - Situations where an increase in plasma levels may occur - Concomitant use of fibrates.

WARNINGS & PRECAUTIONS: Bempedoic Acid: *Hyperuricemia***:** Bempedoic Acid inhibits renal tubular OAT2 and may increase blood uric acid levels. *Tendon Rupture*: Bempedoic Acid is associated with an increased risk of tendon rupture or injury. **Rosuvastatin:** *Skeletal muscle effects (e.g., myopathy and rhabdomyolysis):* Risks increase with use of 40 mg dose, advanced age (≥65), hypothyroidism, renal impairment, and combination use with cyclosporine, darolutamide, regorafenib, certain anti-viral medicines or their combinations. *Liver enzyme abnormalities*: Persistent elevations in hepatic transaminases can occur. Perform liver enzyme tests before initiating therapy and as clinically indicated thereafter. *Concomitant Coumarin Anticoagulants*: Caution should be exercised when anticoagulants are given in conjunction with rosuvastatin because of its potentiation of the effect of coumarin-type anticoagulants in prolonging the prothrombin time/INR. Proteinuria and Hematuria: In the rosuvastatin clinical studies, dipstick-positive proteinuria and microscopic hematuria were observed among rosuvastatin treated patients. Endocrine Effects: Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including rosuvastatin.

DRUG INTERACTIONS: Bempedoic Acid : *Simvastatin:* Concomitant use of Bempedoic Acid with simvastatin causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. *Pravastatin:* Concomitant use of Bempedoic Acid with pravastatin causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. **Rosuvastatin**: Combination of sofosbuvir/velpatasvir/voxilaprevir or ledipasvir/sofosbuvir: Combination increases rosuvastatin exposure. Use with rosuvastatin is not recommended. Cyclosporine and darolutamide: Combination increases rosuvastatin exposure. Limit rosuvastatin dose to 5 mg once daily. Gemfibrozil:

Combination should be avoided. If used together, limit rosuvastatin dose to 10 mg once daily. Atazanavir/ritonavir, lopinavir/ritonavir, simeprevir or combination of dasabuvir/ombitasvir/paritaprevir/ritonavir, elbasvir/grazoprevir, sofosbuvir/velpatasvir and glecaprevir/pibrentasvir: Combination increases rosuvastatin exposure. Limit rosuvastatin dose to 10 mg once daily. Regorafenib: Combination increases rosuvastatin exposure. Limit rosuvastatin dose to 10 mg once daily. Coumarin anticoagulants: Combination prolongs INR. Achieve stable INR prior to starting rosuvastatin. Monitor INR frequently until stable upon initiation or alteration of rosuvastatin therapy. Concomitant lipid-lowering therapies: Use with fibrates or lipid-modifying doses (≥1 g/day) of niacin increases the risk of adverse skeletal muscle effects. Caution should be used when prescribing with rosuvastatin.

ADVERSE REACTIONS: Anaemia, Haemoglobin decreased, Gout, Hyperuricaemia, Aspartate aminotransferase increased, Alanine aminotransferase increased, Liver function test increased, Pain in extremity, Blood creatinine increased, Blood urea increased, Glomerular filtration rate decreased. Thrombocytopenia, Hypersensitivity reactions including angioedema, Diabetes mellitus, Depression, Headache, Dizziness, Polyneuropathy, Mmemory loss, Peripheral neuropathy, sleep disturbances, Cough, Dyspnoea, Constipation, Nausea, Abdominal Pain, Pancreatitis, Diarrhoea, Increased hepatic transaminases, Jaundice, Hepatitis, Pruritus, Rash, Urticarial, Stevens-Johnson syndrome, Myalgia, Myopathy (including myositis), Rhabdomyolysis, Lupus-like syndrome, Muscle rupture, Arthralgia, Immune-mediated necrotizing myopathy, Tendon disorders, Haematuria, Gynaecomastia, Asthenia, Oedema.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/ ROZUCOR B 10 and 20 mg/SEP-2024/01/ABPI

(Additional information is available on request)